In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 22-0390V

MARK HUMPFER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: January 8, 2025

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Alec Saxe, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On April 4, 2022, Mark Humpfer filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of an influenza ("flu") vaccine received on November 8, 2020, he suffered a shoulder injury related to vaccine administration ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1). The claim was assigned to the Office of Special Masters ("OSM")'s Special Processing Unit ("SPU") in June 2022, and the parties' initial settlement discussions were unsuccessful. Accordingly, they proposed the submission of Respondent's Rule 4(c) Report (ECF No. 27), followed by briefing of their respective positions (ECF Nos. 31, 33, 37).

[1] Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Because the record supports the conclusion that Petitioner's pain was not limited to the affected shoulder (under the meaning of 42 C.F.R. § 100.3(c)(10)(iii)), I hereby dismiss the Table SIRVA claim – although a possibly-meritorious causation-in-fact claim remains.

I. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). Compensation may not be awarded "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A potential petitioner must demonstrate that he or she "suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." Section 11(c)(1)(D)(i)[3]; *see also Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied,* 132 S.Ct. 1908 (2012); *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

Beyond severity and other requirements concerning the vaccination received, and the lack of other award or settlement, *see* Section 11(c)(1)(A), (B), (D), and (E), a petitioner must establish that he or she either suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

[3] Section 11(c)(1)(D) presents two alternative grounds for eligibility to compensation if a petitioner does not meet the six months threshold: (ii) death from the vaccine, and (iii) inpatient hospitalization and surgical intervention. Neither alternative is alleged or implicated in this claim.

The most recent version of the Vaccine Injury Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Pursuant to the Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

If the petitioner's injury does not fit within a Table listing, the petitioner must prove that the administered vaccine was the cause in fact of the injury. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove the claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.*

II. Evidence

I have reviewed all submitted evidence including all medical records and affidavits, as well as the Petition, the Rule 4(c) Report, and both parties' briefing.

Petitioner was born in 1956, and had no history of right upper extremity pain or dysfunction or any other relevant conditions. *See generally* Ex. 3 at 1 – 387. He received the at-issue flu vaccine on November 8, 2020, at a CVS pharmacy location in Indiana. While a computerized record suggests that his left deltoid as the situs (Ex. 2 at 2), the pharmacist later signed a handwritten notation supporting a right-sided administration (Ex. 8 at 1 – 2).

Nearly two months later, on December 28, 2020, Petitioner saw his established primary care physician ("PCP") for a chief complaint of "R arm pain… present since getting flu shot in November… hurts to lift R arm." Ex. 3 at 396. The physical examination found only "tender[ness] along medial[4] aspect of R biceps," but did not document range of motion ("ROM") issues. *Id.* at 401. The PCP's assessment was right upper extremity pain, for which Petitioner should take prednisone. *Id.*

On January 4 and 22, 2021, Petitioner telephoned his PCP to report continued "arm pain." Ex. 10 at 21, 70. On February 9, 2021, Petitioner reported "right upper arm pain… a lot of pain at night. Or if he rises arm above [t]he head." *Id.* at 97. At that point, the PCP recommended an orthopedics consult. *Id.*

[4] Medial is defined as "pertaining to the middle; closer to the median plane or the midline of a body or structure." *Dorland's Medical Dictionary Online (hereinafter "Dorland's")*, https://www.dorlandsonline.com/dorland/definition?id=30006&searchterm=medial (last accessed Jan. 3, 2025).

On February 16, 2021, an orthopedist conducted the initial evaluation of "[Petitioner's] right upper arm/ right elbow pain. He states the pain started following his flu shot on 11/08/21. He states that the arm was very sore following [the vaccination?] and he is now having sharp shooting pains that start in the biceps area and shoot down to his elbow. He states that the pain comes and goes depending on what he is doing. Difficulty is found in lifting, pushing, and pulling. His ROM is limited due to the pain." Ex. 4 at 19. Examination of the right elbow found mild lateral epicondyle tenderness, normal ROM; full strength; a positive resisted wrist test; and lateral epicondyle pain upon dorsiflexion. *Id.* at 20.

The orthopedist's examination of the right shoulder found mild tenderness on the "proximal shoulder"; "normal ROM [range of motion] in comparison to contralateral side"; mild weakness (-4/5 "+ pain"); and positive empty-can, lift-off, Hawkins, Neer's, and Speeds tests. Ex. 4 at 20. X-rays of the shoulder and elbow were obtained. *Id.* at 21. The orthopedist's diagnoses were right elbow pain, right elbow lateral epicondylitis, right shoulder impingement syndrome, and right shoulder bicipital tendinitis. *Id.* The orthopedist administered a steroid injection to the right shoulder's subacromial space and entered a referral to physical therapy ("PT"). *Id.*

At the February 23, 2021, PT initial evaluation,[5] Petitioner recounted developing "sharp pains in the upper arm after he received his flu shot. Pain has not changed since it started. Tends to keep the arm rotated into his body." Ex. 4 at 8. In addition, however, he also "describe[d] sharp pains throughout the upper arm and elbow. Modifies his pain in order to decrease or to not provoke pain… [Petitioner] did not have any change of pain with the subacromial injection…" *Id.* He rated his "right biceps" pain at 3 – 10/10. *Id.* at 8.

The physical therapist's examination findings included: "Biceps pain provoked with gripping. Sharp shooting pains through biceps with shoulder flexion and slightly less pain with shoulder abduction…" Ex. 4 at 8. The shoulder's active ROM was limited (*e.g.,* 110 degrees on abduction, 22 degrees on external rotation, 90 degrees on flexion). *Id.* at 8. There was tenderness at the anterior shoulder, as well as minimally throughout the biceps and at the lateral epicondyle of the elbow. *Id.* The therapist summarized: "Pt's right upper arm pain is irritable and limiting all… functional motion of the RUE [right upper extremity]. He has pain in all planes, guarded posturing, and limited PROM. At this point, [Petitioner's] condition is too painful to narrow down exactly what structures are involved." *Id.* at 9.

[5] The PT record also lists a medical diagnosis of "bicipital tendinitis, right shoulder"; a treatment diagnosis of "pain in right shoulder," and a chief complaint of "constant shoulder pain." Ex. 4 at 7.

The physical therapist formulated a treatment plan featuring hot and cold packs; electrical stimulation; ultrasound and phonopheresis; and a home exercise program ("HEP"). Ex. 4 at 9. By the 15th formal PT session on April 26, 2021, Petitioner had not achieved all goals – but because his insurance coverage had run out, he was discharged with an updated HEP. Ex. 5 at 20 – 20; *see also id.* at 59 (Petitioner's later report that he "stopped attending therapy due to insurance not covering the cost").

At his first orthopedics follow-up on July 7, 2021, Petitioner's history was largely identical to that from the initial evaluation – with an additional reference to the steroid injection providing "minimal relief." Ex. 5 at 62. The examination findings at the elbow were unchanged. *Id.* at 63. The shoulder had decreased ROM (flexion to 160 degrees and abduction to 90, with pain at extremes); guarding; and "notable… hiking." *Id.* The orthopedist recorded that Petitioner would "continu[e] conservative treatment of his elbow for his medial lateral epicondylitis." *Id.* He added diagnoses of right shoulder primary arthritis and adhesive capsulitis, and he ordered an MRI of the shoulder to guide further treatment thereof. Ex. 5 at 63.

At the next orthopedics follow-up on July 28, 2021, Petitioner reported continued pain rating up to 9/10, including the specific complaint that he was "unable to bend the elbow without feeling pain." Ex. 5 at 59. However, the orthopedist limited his examination to the shoulder, and reviewed that "[Petitioner] continues to have diffuse non-specific shoulder pain." *Id.* at 60. The orthopedist reviewed that a shoulder MRI had visualized "various rotator cuff pathology including subscapularis tendinosis, hypertrophic changes at the acromioclavicular joint which deforms the rotator cuff, [diffuse] degeneration and tear of the posterior labrum, biceps tenosynovitis, as well as chronic capsulitis in the rotator cuff interval." Ex. 5 at 60; *see also id.* at 18 (July 23, 2021, MRI report). On August 3, 2021,[6] the orthopedist administered another steroid injection to the shoulder's subacromial space and authorized another course of PT. Ex. 5 at 57.[7]

At an August 16, 2021, PT reevaluation, Petitioner denied any "difference" since the recent steroid injection. Ex. 5 at 14. He reported: "[T]ightness through the elbow, tightness in the shoulder. Intermittent shooting pain in the upper arm/ biceps and elbow with putting seat belt on, reaching above head to turn off light, reaching in backseat of vehicle…" *Id.* He also rated his "right upper arm/ elbow" pain at 0 – 9/10. On exam, the elbow had no ROM restrictions, but mild weakness. *Id.* at 14 – 15. The shoulder's ROM

[6] It is noted that Petitioner requested time to get "on Medicaid" prior to receiving the steroid injection and reauthorization for PT. Ex. 5 at 61. But subsequent medical records do not reference Medicaid – and Petitioner has represented that the case does not involve a Medicaid lien. Brief at 37; *see also* Status Report filed Feb. 13, 2023 (ECF No. 17) at 2.

[7] There are no further orthopedic encounters.

was reduced and painful ("located through biceps"), with positive impingement signs. *Id.* at 14 – 15. There was also "tenderness to the long head of biceps, biceps muscle belly (entire length), to cubital fossa." *Id.* at 15. Petitioner was discharged after 15 additional PT sessions, on October 14, 2021. Ex. 6 at 6 – 8.

There is no further medical record documentation of treatment obtained for Petitioner's right upper extremity. Ex. 6 at 45 – 47 (October 11, 2021, encounter with a different orthopedist, regarding knee pain, which was attributed to osteoarthritis and obesity); Ex. 11 (list of Cryofreeze sessions occurring from November 2021 – February 2023, without identification of the body part(s) treated); *but see* Ex. 12 at ¶¶ 16 – 20 (Petitioner's explanation that the Cryofreeze sessions were for his shoulder).

I have also reviewed Petitioner's initial sworn declaration from March 2022 (Ex. 1), and Petitioner and several other witnesses' supplemental declarations prepared in early 2024 (Exs. 12 – 17). The declarations tend to refer to pain being located in the right shoulder, which made it difficult for Petitioner to utilize his arm.

III. Analysis

Petitioner's Table SIRVA claim is not feasible, because he has not established that his "pain and limited range of motion [were] limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii).

I have previously observed that "claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body, since the essence of the claim is that a vaccine administered to the shoulder primarily caused pain there." *Cross v. Sec'y of Health & Hum. Servs.*, No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Dec. 2, 2022); *see also, e.g.*, *K.P. v. Sec'y of Health & Hum. Servs.*, No. 19-65V, 2022 WL 3226776, at * (Fed. Cl. Spec. Mstr. May 25, 2022) (finding that the third QAI requirement was met notwithstanding "stray notations of pain extending beyond the shoulder"); cited in Response at 7. However, and depending on the totality of the evidence, a claimant's medical records can also support the determination that pain and other issues are equally or predominantly related to other aspects of the individual's arm or body, undermining a key SIRVA requirement.

Here, Mr. Humpfer's initial PCP evaluation and three follow-up telephone messages are somewhat unspecific in describing "arm pain" and "upper arm pain" especially when it was lifted. *See* Ex. 3 at 396; Ex. 10 at 21, 70, 97. Those notations, standing alone, could be understood as describing pain at the shoulder. But it is also significant that the PCP's examination was remarkable only for medial biceps tenderness,

Ex. 3 at 396. In contrast, no *shoulder* tenderness, pain, or limited range of motion was documented on that same exam.

More problematic are the later medical records which consistently describe Petitioner's pain as being localized below the shoulder, specifically at the biceps. *See, e.g.*, Ex. 4 at 19 (orthopedics initial evaluation, noting that "the arm was very sore… he is now having sharp shooting pains that start in the biceps area and shoot down to the elbow"); *id.* at 8 "(PT initial evaluation, recounting "Sharp pains in the upper arm after receiving the flu shot. Pain has not changed since it started"); *id.* (rating "right biceps" pain reaching 10/10); Ex. 5 at 15 (PT reevaluation finding tenderness throughout the biceps' "entire length"). And Petitioner confirms that anatomically, "the biceps tendons attach the biceps muscle to bones in the shoulder and elbow." Reply at 2. Therefore, the "biceps" complaints in this case *possibly included* the shoulder, but were necessarily *not* "limited to the shoulder," as the QAI's language requires.

Petitioner contends that his "biceps pain was a result of movement and pain with the shoulder," and thus that shoulder pain was the epicenter of his concerns. Brief at 18. But the same "biceps pain" was provoked upon a grip-strength test (Ex. 4 at 8), which would not be expected to engage the shoulder more than indirectly.[8]

Thus, unlike cases such as *Cross* and *K.P.*, the record herein contains preponderant evidence of pain not being limited to the shoulder, but instead primarily occurring below the shoulder at the biceps and extending at times to the elbow.[9] This means a SIRVA Table element cannot be met.

Conclusion and Scheduling Order

For the foregoing reasons, Petitioner has not established 42 C.F.R. § 100.3(c)(10)(iii) and therefore his Table SIRVA claim must be **DISMISSED.**

Respondent also contends that Petitioner has not preponderantly established that his pain began within forty-eight (48) hours post-vaccination. Rule 4(c) Report at 8 – 10; Response at 2 – 4. At this time, I will preliminarily note that Petitioner's 50-day initial

[8] *See Grip Strength*, https://www.physio-pedia.com/Grip_Strength (last accessed Jan. 7, 2024) (defining grip strength as "a measure of muscular strength or the maximum force/tension *generated by one's forearm muscles*… normally measured by a handheld dynamometer") (emphasis added).

[9] Also distinguishable is another case which included better medical record notations of pain occurring "*from shoulder* down towards her upper arm…" notwithstanding a similar assessment of bicipital tendinitis. *Valdez v. Sec'y of Health & Hum. Servs.*, No. 21-394V, 2024 WL 1526536, at *2 (Fed. Cl. Spec. Mstr. Feb. 28, 2024), cited in Reply at 2.

treatment delay is not obviously unreasonable, and once he sought treatment, he consistently related his injury back to the vaccination, and without suggesting any delayed or attenuated timeframe. Therefore, Respondent may not prevail in establishing an onset that further weakens Petitioner's claim.

Petitioner has also "reserve[d] the right to retain an expert to further substantiate any *Althen* prong, should the Court find that Petitioner did not satisfy the SIRVA Table requirements." Brief at 26. If and when authorized to opine in the case, qualified medical experts may be able to address the relevant anatomy (including of the biceps being attached to the shoulder) and causation-in-fact for the injury shown herein. *See also* Response at 6 (opposing Petitioner's "lay hypotheses" on these subjects). But experts are not typically authorized in SPU, and I do not find them particularly warranted here, when considering even the case's "full value." The parties are encouraged to promptly revisit their settlement discussions. If a tentative settlement agreement cannot be reached by the following deadline, the case will be immediately transferred out of SPU to a Special Master for further proceedings.

In accordance with the above, by no later than Monday, February 24, 2025, Petitioner shall file a Joint Status Report updating on the case, unless a 15-Week Order has been requested by that deadline.[10]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[10] Petitioner previously reported that the case does not involve a Medicaid lien. Scheduling Order filed Feb. 13, 2023 (ECF No. 17).